

Amendments Proposed to Massachusetts' Determination of Need Regulation

The Massachusetts Department of Public Health ("DPH") recently issued proposed amendments to the Determination of Need ("DON") Regulation, 105 C.M.R. 100.000, making a number of substantive changes and clarifying certain existing DPH policies. DPH will hold a public hearing on the proposed amendments on May 20, 2008. A copy of the proposed amendments and related materials may be accessed by [clicking here](#).

One set of proposed changes to the DON Regulation responds to DPH's concern about the negative impacts on community hospitals resulting from the expansion of Boston academic medical centers into suburban communities. In particular, the proposed amendments make clear that a DON must be filed when a hospital seeks to open a new inpatient satellite or move inpatient beds to an existing outpatient satellite. In addition, as amended, the DON Regulation would identify "non-duplication of services" as a separate review factor in a DON application, giving it equal weight with other factors considered in DONs. Thus, under the proposed amendments, DPH could deny an application to open a new inpatient satellite or to move inpatient beds to an existing outpatient satellite if it determined that existing community hospitals in the satellite's area had sufficient inpatient capacity.

The proposed amendments to the DON Regulation include a number of other changes. First, DPH proposes to eliminate as of August 1, 2008 the ability of physicians to rely on unimplemented letters of intent that, if filed before certain dates in 1991 and 1993, permitted physicians to acquire MRI technology, PET scanning and radiation therapy and certain other technologies without obtaining a DON. DPH also proposes to treat implementation of innovative new services or acquisitions of new technology obtained pursuant to such letters of intent as if they were acquired pursuant to a DON. Thus, expansions of, transfers of ownership of, or transfers of site for such new services or technology would require a DON.

In addition, DPH proposes to make certain modifications to the so-called Section 308 exemption process for certain projects that do not involve substantial capital expenditures and that involve a substantial change in services or original licensure for a freestanding ambulatory surgery center from the DON requirements. Under the proposed revisions, DPH may attach conditions on granting Section 308 exemptions, including a condition relating to community initiatives. Also, rather than always requiring an applicant to submit a full DON application when a person intends to continue a project exempted under Section 308 for more than a year, DPH proposes that a full DON application only be required upon DPH's request.

Consistent with proposed changes to the regulations governing substance abuse programs and facilities, the proposed amendments to the DON Regulation remove references to DON review for such projects.

Finally, the proposed amendments "clarify" certain of DPH's existing policies. First, the proposed amendments explicitly provide that build out of shell space is a significant change to a project. Second, when a party builds out shell space associated with a project that did not require a DON because it was below the expenditure minimum, the party must seek a determination from DPH as to whether the project in its entirety would require a DON.

If you have any questions concerning the proposed amendments to the DON Regulation, please contact your regular Ropes & Gray attorney.

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